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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/807,660

09/06/2001

Richard B. Gayle III

P23,495 USA

2232

7590

08/01/2006

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EXAMINER

HUYNH, PHUONG N

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,660

Applicant(s)

GAYLE III ET AL.

Examiner

Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5, 7 and 19-41 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7,20,21 and 26-41 is/are rejected.
- 7) ☒ Claim(s) 22-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-3, 5, 7 and 19-41 are pending.
2. Claim 19 stands withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to a non-elected invention.
3. In view of the amendment filed 4/18/06, the following objection remains.
4. The drawings, filed 4/16/01, stand not approved because the background of Figure 4 is too dark. Applicants stated that another copy of the Figure 4 was enclosed with this reply. However, such Figure is not found.
5. The following new grounds of rejections are necessitated by the amendment filed 4/18/06.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 1-3, 20, 26, 28, 30, 32, 34, 36, 38, and 40 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The "...1-15 of SEQ ID NO: 6, 25-36 of SEQ ID NO: 28, 27-34 of SE QID NO: 29, 21-24 of SEQ ID NO: 30..." in claims 1, and 3 represents a departure from the specification and the claims as originally fled. The passages pointed out by applicant in the amendment filed 4/18/06 do not provide a clear support for the said phrase.

The "39-476 of SEQ ID NO: 2" in claim 2 represents a departure from the specification and the claims as originally fled. The passages pointed out by applicant in the amendment filed 4/18/06 do not provide a clear support for the said phrase. The specification at page 39, line 36 discloses 49-476 of SEQ ID NO: 2.

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8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-3, 5, 7, 20-21, and 26-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of (1) any soluble CD39 comprising any heterologous peptide X selected from the group consisting of "amino acids 1-15 of SEO ID NO:6. amino acids 25-35 of SEO ID NO:28, amino acids 27-34 of SEO ID NO:29. and amino acids 21-24 of SEO ID NO:30" fused to any Y polypeptide selected from the group consisting of a) a polypeptide consisting of amino acids 36-478 of SEO ID NO:2; (b) a fragment of the polypeptide of (a) consisting of consecutive amino acids of (a) wherein said fragment has apyrase activity; (c) a variant polypeptide that is at least 95% identical in amino acid sequence to (a) or (b) wherein said variant polypeptide has apyrase activity and (d) a substituted polypeptide consisting of the amino acids of (a), (b), or (c) with at least one conservative amino acid substitution wherein said substituted polypeptide has apyrase activity for the claimed method, (2) any soluble CD39 comprising any heterologous peptide X selected from the group consisting of "amino acids 1-15 of SEO ID NO:6. amino acids 25-35 of SEO ID NO:28, amino acids 27-34 of SEO ID NO:29. and amino acids 21-24 of SEO ID NO:30" fused to Y polypeptide consisting of "39-476 of SEQ ID NO: 2" for the claimed method, and (3) any soluble CD39 polypeptide selected from the group consisting of amino acids "25-474 of SEQ ID NO: 28", amino acids "27-473 of SEQ ID NO: 29" and amino acids "21-463 of SEQ ID NO: 30" for the claimed method of inhibiting platelet activation and recruitment.

The specification discloses only a method for inhibiting platelet activation and recruitment by administering the specific soluble human CD39 such as the ones disclosed at page 37-40 of the specification. With the exception of the specific soluble human CD39 fusion protein comprising SEQ ID NO: 6 encoded by SEQ ID NO: 5 or 7 mentioned above for the claimed method of inhibiting platelet activation, there is insufficient written description about the specific amino acid residues such as "amino acids 1-15 of SEO ID NO:6. amino acids 25-35 of SEO ID NO:28, amino acids 27-34 of SEO ID NO:29. and amino acids 21-24 of SEO ID NO:30" fused to

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any Y polypeptide selected from the group consisting of a) a polypeptide consisting of amino acids 36-478 of SEQ ID NO:2; (b) a fragment of the polypeptide of (a) consisting of consecutive amino acids of (a) wherein said fragment has apyrase activity; (c) a variant polypeptide that is at least 95% identical in amino acid sequence to (a) or (b) wherein said variant polypeptide has apyrase activity and (d) a substituted polypeptide consisting of the amino acids of (a), (b), or (c) with at least one conservative amino acid substitution, let alone the soluble CD39 polypeptide inhibits platelet activation and recruitment.

Further, the specification does not adequately describe the soluble CD39 polypeptide selected from the group consisting of amino acids “25-474 of SEQ ID NO: 28”, amino acids “27-473 of SEQ ID NO: 29” and amino acids “21-463 of SEQ ID NO: 30” for the claimed method (claims 5 and 7). Further, the term “has” is open-ended. It expands the residues 21-463 of SEQ ID NO: 30 to include additional amino acids at either or both ends. There is inadequate written description about the amino acids to be added. Since the X and Y mentioned above in the soluble CD39 polypeptide are not adequately described, it follows that the method of using such soluble CD39 is not adequately described.

10. Claims 22-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
11. No claim is allowed.
12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

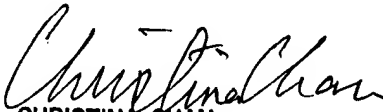
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.
14. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

July 21, 2006


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